



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-37, CMS-64, CMS-10052, CMS-10141, CMS-10142, CMS-10227, CMS-10311, CMS-10344, CMS-10500, CMS-R-26, CMS-R-138, CMS-R-244, and CMS-R-308]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **Insert date 60 days after date of publication in the Federal Register**:

ADDRESSES: When commenting, please reference the document identifier or OMB control

number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. E-mail your request, including your address, phone number, OMB number, and CMS

document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-37    Medicaid Program Budget Report

CMS-64    Medicaid Program Budget Report

CMS-10052        Recognition of Pass-Through Payment for Additional (New) Categories of  
Devices Under the Outpatient Prospective Payment System and Supporting Regulations

CMS-10141        Medicare Prescription Drug Benefit Program

CMS-10142        Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and  
Prescription Drug Plans (PDP)

CMS-10227        PACE State Plan Amendment Preprint

CMS-10311        Medicare Program/Home Health Prospective Payment System Rate  
Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation

CMS-10344        Elimination of Cost-Sharing for full benefit dual-eligible Individuals  
Receiving Home and Community-Based Services

CMS-10500        Outpatient and Ambulatory Surgery Experience of Care Survey

CMS-R-26        Clinical Laboratory Improvement Amendments (CLIA) Regulations

CMS-R-138        Medicare Geographic Classification Review Board (MGCRB) Procedures  
and Supporting Regulations

CMS-R-244        Programs for All-inclusive Care of the Elderly (PACE) and Supporting  
Regulations

CMS-R-308        State Children's Health Insurance Program and Supporting Regulations

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collections

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicaid Program Budget Report; Use: We require that each State Medicaid agency quarterly submit the Form CMS-37 via the web-based Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES). Due dates are November 15, February 15, May 15 and August 15 of each fiscal year. The addendum provides a description of forms contained in this package. All submissions represent equally important components of the grant award cycle, but the May and November submissions are particularly significant for budget formulation. The November submission introduces a new fiscal year to the budget cycle and serves as the basis for the formulation of the Medicaid portion of the President's Budget, which is presented to Congress in January. The February and August submissions are used primarily for budget execution in providing interim updates to CMS' Office of Financial Management, the Department of Health and Human Services, the Office of Management and Budget and Congress depending on the scheduling of the national budget

review process in a given fiscal year. These submissions provide us with base information necessary to track current year obligations and expenditures in relation to the current year appropriation and to notify senior managers of any impending surpluses or deficits; Form Number: CMS-37 (OCN: 0938-0101); Frequency: Quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 224; Total Annual Hours: 7,616 (For policy questions regarding this collection contact Abraham John at 410-786-4519).

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicaid Program Budget Report; Use: Section 1903 of the Social Security Act provides the authority for collecting this information. States are required to submit the form CMS-64 quarterly to us no later than 30 days after the end of the quarter being reported. These submissions provide us with the information necessary to issue the quarterly grant awards, monitor current year expenditure levels, determine the allow ability of State claims for reimbursement, develop Medicaid financial management information provide for State reporting of waiver expenditures, ensure that the federally-established limit is not exceeded for HCBS waivers, and to allow for the implementation of the Assignment of Rights and Part A and Part B Premium (i.e., accounting for overdue Part A and Part B Premiums under State buy-in agreements)--Billing Offsets. Form Number: CMS-64 (OCN: 0938-0067); Frequency: Quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 224; Total Annual Hours: 16,464. (For policy questions regarding this collection contact Abraham John at 410-786-4519).

3. Type of Information Collection Request: Extension without change of a currently approved collection; Title of Information Collection: Recognition of Pass-Through Payment for

Additional (New) Categories of Devices Under the Outpatient Prospective Payment System and Supporting Regulations; Use: Interested parties such as hospitals, device manufacturers,

pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient prospective payment system (PPS).

After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories. We list below the information that we require from all applicants. Form Number: CMS-10052

(OCN: 0938-0857); Frequency: Once; Affected Public: Business or other for-profits; Number of Respondents: 10; Total Annual Responses: 10; Total Annual Hours: 160. (For policy questions regarding this collection contact Barry Levi at 410-786-4529).

4. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Prescription Drug Benefit Program; Use: Part D plans use the information to comply with the eligibility and associated Part D participating requirements. We use the information to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and to ensure that correct information is disclosed to potential and current enrollees. Form Number: CMS-10141 (OCN: 0938-0964); Frequency: Occasionally; Affected Public: Individuals or households, Business or other for-profits and Not-for-profit institutions, and State, Local, or Tribal Governments; Number of Respondents: 4,100,953; Total Annual Responses: 26,301,339; Total Annual Hours: 7,572,243. (For policy questions regarding this collection contact Deborah Larwood at 410-786-9500).

5. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); Use: We require Medicare Advantage organizations (MAOs) and prescription drug plans (PDPs) to complete the BPT as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to us for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. The BPT calculates the plan's bid, enrollee premiums, and payment rates. We publish beneficiary premium information using a variety of formats (www.medicare.gov, the Medicare & You handbook, Summary of Benefits marketing information) for the purpose of beneficiary education and enrollment. Form Number: CMS-10142 (OCN-0938-0944); Frequency: Yearly; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 555; Total Annual Responses: 4,995; Total Annual Hours: 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410-786-3026).

6. Type of Information Collection Request: Extension without change of a currently approved collection; Title of Information Collection: PACE State Plan Amendment Preprint; Use: If a state elects to offer PACE as an optional Medicaid benefit, it must complete a state plan amendment preprint packet described as "Enclosures #3,4,5,6 and 7." The information, collected from the state on a one-time basis is needed in order to determine if the state has properly elected to cover PACE services as a state plan option. Form Number: CMS-10227 (OCN: 0938-1027); Frequency: Once and occasionally; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 21; Total Annual Responses: 7; Total Annual Hours: 240. (For policy questions regarding this collection contact Angela Taube at 410-786-2638).

7. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Program - Home Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation; Use: The conditions of participation and accompanying requirements specified in the regulations are used by Federal or state surveyors as a basis for determining whether a home health agency qualifies for approval or re-approval under Medicare. The Physician's certification and recertification of each patient's need for skilled care services; homebound status and the physician's clinical justification for skilled nursing management and evaluation of the care plan specified in the regulations at 42 CFR 424.22 are to be used by contractors and by us when reviewing the patient's medical record as a basis for determining whether the patient is eligible for the Medicare home health benefit and whether the medical record meets the criteria for coverage and Medicare payment. We, along with the healthcare industry believe that the availability to the home health agency of the type of records and general content of records, which this regulation specifies, is standard medical practice, and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. Form Number: CMS-10311 (OCN: 0938-1083; Frequency: Occasionally; Affected Public: Business or other for-profits and Not-for-profit institutions); Number of Respondents: 9,354; Total Annual Responses: 345,600; Total Annual Hours: 28,800. (For policy questions regarding this collection contact Randy Thronset at 410-786-0131).

8. Type of Information Collection Request: Extension without change of a currently approved collection; Title of Information Collection: Elimination of Cost-Sharing for full benefit dual-eligible Individuals Receiving Home and Community-Based Services; Use: This provision eliminates Part D cost-sharing for full benefit dual-eligible beneficiaries who are receiving home



and community based services. To implement this provision, States are required to identify the affected beneficiaries in their monthly Medicare Modernization Act Phase Down reports. Form Number: CMS-10344 (OCN: 0938-1127); Frequency: Monthly; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 51; Total Annual Responses: 612; Total Annual Hours: 612. (For policy questions regarding this collection contact Katherine Pokrzywa at 410-786-5530).

9. Type of Information Collection Request: New collection (Request for a new control number); Title of Information Collection: Outpatient and Ambulatory Surgery Experience of Care Survey; Use: We will use the information collected through the field test to inform the development of a larger national survey effort, including development of the final survey instrument and data collection procedures. Looking toward the survey development specifically, the data collected in this survey effort will be used to conduct a rigorous psychometric analysis of the survey content. The goal of such an analysis is to assess the measurement properties of the proposed instrument and sub-domain composites created from item subsets, to assure the information reported from any future administrations of the survey is well-defined. Such careful definition will prevent data distortion or misinformation if they are publicly reported. Data collection procedures will also be fine-tuned during this field test. Form Number: CMS-10500 (OCN: 0938-New); Frequency: Once; Affected Public: Individuals and households; Number of Respondents: 2,304; Total Annual Responses: 2,304; Total Annual Hours: 384. (For policy questions regarding this collection contact Caren Ginsberg at 410-786-0713).

10. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Clinical Laboratory Improvement Amendments (CLIA) Regulations; Use: The information is necessary to determine an entity's compliance with the

Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA). In addition, laboratories participating in the Medicare program must comply with CLIA requirements as required by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements. Form Number: CMS-R-26 (OCN: 0938-0612); Frequency: Monthly, occasionally; Affected Public: Business or other for-profits and not-for-profit institutions, State, Local or Tribal Governments, and the Federal government; Number of Respondents: 79,175; Total Annual Responses: 88,886,364; Total Annual Hours: 15,613,299. (For policy questions regarding this collection contact Raelene Perfetto at 410-786-6876).

11. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting Regulations; Use: The information submitted by the hospitals is used to determine the validity of the hospitals' requests and the discretion used by the Medicare Geographic Classification Review Board (MGCRB) in reviewing and making decisions regarding hospitals' requests for geographic reclassification. Form Number: CMS-R-138 (OCN: 0938-0573); Frequency: Yearly; Affected Public: Business or other for-profits and Not-for-profit institutions, and State, Local, or Tribal Governments; Number of Respondents: 300; Total Annual Responses: 300; Total Annual Hours: 300. (For policy questions regarding this collection contact Geri Mondowney at 410-786-1172).

12. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Programs for All-inclusive Care of the Elderly (PACE) and Supporting Regulations; Use: The PACE organizations must demonstrate their ability to provide quality community-based care for the frail elderly who meet their state's nursing home eligibility

standards using capitated payments from Medicare and the state. The model of care includes as core services the provision of adult day health care and multidisciplinary team case management, through which access to and allocation of all health services is controlled. Physician, therapeutic, ancillary, and social support services are provided in the participant's residence or on-site at the adult day health center. The PACE programs must provide all Medicare and Medicaid covered services including hospital, nursing home, home health, and other specialized services. Financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments. The information collection requirements are necessary to ensure that only appropriate organizations are selected to become PACE organizations and that we have the information necessary to monitor the care provided to the frail, vulnerable population served. Form Number: CMS-R-244 (OCN: -0938-0790; Frequency: Once and occasionally; Affected Public: Private Sector (Not-for-profit institutions); Number of Respondents: 99; Total Annual Responses: 99; Total Annual Hours: 81,912. (For policy questions regarding this collection contact Anitra Johnson at 410-786-0609).

13. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: State Children's Health Insurance Program and Supporting Regulations; Use: States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private

coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage. Form Number: CMS-R-308 (OCN: 0938-0841; Frequency: Yearly, once, and occasionally; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 400; Total Annual Hours: 1,489,092. (For policy questions regarding this collection contact Judith Cash at 410-786-4473).

Dated: September 30, 2013

\_\_\_\_\_

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

[FR Doc. 2013-24250 Filed 10/03/2013 at 8:45 am; Publication Date: 10/04/2013]